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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Gregory et. al. Examiner: Dr. K. C. Carlson
Serial No.: 08/087,132 Art Unit: 1812
Filed: July 2, 1993 Docket: IG4-9.2(FWC)

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For: NEW DIAGNOSTIC AND TREATMENT METHODS
INVOLVING THE CYSTIC FIBROSIS TRANSMEMBRANE
REGULATOR

AUG 21 1995

GROUP 1800

Honorable Commissioner of
Patents and Trademarks
Washington, DC 20231

SUPPLEMENTAL REPLY UNDER 37 CFR 1.111

SIR:

This Supplemental Reply is further to the Reply with Amendment that was submitted on June 9, 1995 in response to the Examiner's Action herein of December 9, 1994. The Examiner's considerable efforts on behalf of the Application are again acknowledged. In particular, the Interview of November 23, 1994 was greatly appreciated.

Preliminary Consideration

A few typographical errors were noted in the text of Applicants' "Reply with Amendment" that was submitted herein on June 9, 1995. The Examiner's attention is respectfully directed to the following errors in that Reply.

- (1) At page 14, lines 4-5 of the Reply, "Document (B)" should have read "Riordan et al. 1989".
- (2) At page 23, in the first full paragraph thereof, at the second line of the paragraph, the phrase "Documents (E) or (F)" should have read "Documents (C) or (E)".

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(3) At page 23, in the first full paragraph thereof, at the fifth line thereof, the phrase "Document (E)" should have read "Document (C)".

(4) At page 23, in the first full paragraph thereof, at the fifth line thereof, the phrase "Document (F)" should have read "Document (E)".

Introduction

This Supplemental Reply is being filed to address the following points:

(I) A limited number of additional claims is being added and a brief discussion thereof is provided.

(II) As was mentioned in the Interview of November 23, 1994, certain old rejections have been made of record in the file of this application (or the parent applications thereof) that may relate to the subject matter of the now-pending claims. Given the long history of the case, and since resolution of those rejections may not have been made, certain of them are listed and discussed below so that the Examiner can confirm that such rejections are either irrelevant to the claims that are now pending, or have been successfully overcome.

(III) Further information is being provided concerning Applicants' reduction to practice of inventions relating to the T to C mutation at nucleotide position 936 in CFTR cDNA. In this regard, a **Rule 1.131 Declaration of Dr. Richard Gregory** is submitted herewith.

(IV) Review of notes taken by Dr. Alan E. Smith of Genzyme Corporation, Assignee of record herein, at two conferences on cystic fibrosis research that were held during the period of April-June 1990 indicates the making at those conferences of certain oral remarks by Dr. Lap-Chee Tsui, a co-inventor/co-author of many of the documents found in the Exhibit Book submitted herein on June 9, 1995. The remarks pertain to Dr. Tsui's then-current attempts to construct a full-length CFTR-encoding cDNA. The remarks are believed to present a very confused picture of Dr. Tsui's in-progress experiments, and thus not to describe any inventions with respect to CFTR-encoding DNA stabilized for propagation in E. coli. Pursuant to Rule 1.56, those remarks, as recorded in Dr. Smith's notes and certain published conference materials, are being called to the Examiner's attention via a **Supplemental Information Disclosure Statement** and a **Rule 1.131 Declaration of Dr. Alan E. Smith**, that are submitted herewith.